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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HORIZON PHARMA IRELAND LIMITED, HZNP LIMITED and HORIZON PHARMA USA, INC., *Plaintiffs,* v. WATSON LABORATORIES, INC., ACTAVIS, INC. and ACTAVIS PLC, *Defendants.*	CIVIL ACTION No. Document Filed Electronically **COMPLAINT FOR PATENT INFRINGEMENT**

COMPLAINT

Plaintiffs Horizon Pharma Ireland Limited, HZNP Limited and Horizon Pharma USA, Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action

against Defendants Watson Laboratories, Inc., Actavis, Inc., and Actavis plc (collectively, "Defendants"), and hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, arising from Defendants' filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Plaintiffs' pharmaceutical product PENNSAID® (diclofenac sodium topical solution) 2% w/w ("PENNSAID® 2%") prior to the expiration of United States Patent Nos. 8,217,078 ("the '078 patent"), 8,252,838 ("the '838 patent"), 8,546,450 ("the '450 patent"), 8,563,613 ("the '613 patent"), 8,618,164 ("the '164 patent") and 8,871,809 ("the '809 patent"), which cover PENNSAID® 2% and its use.

THE PARTIES

2. Plaintiff Horizon Pharma Ireland Limited is a corporation organized and existing under the laws of Ireland, with a principal place of business at Adelaide Chambers, Peter Street, Dublin 8, Ireland.

3. Plaintiff HZNP Limited is a nonresident Irish company that is a tax resident of Bermuda, with a principal place of business at 21 Laffan St., Hamilton, Pembroke, Bermuda HM09.

4. Plaintiff Horizon Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois.

5. On information and belief, Defendant Watson Laboratories, Inc. ("Watson") is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

6. On information and belief, Watson admitted in *Celgene Corp. v. Natco Pharma Ltd.*, Civil Action No. 14-3126 (D.N.J.) that Watson has a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. On information and belief, Watson is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions.

8. On information and belief, Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, 07054.

9. On information and belief, Actavis, Inc. is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions and through the actions of its agents and subsidiaries, including, at least, Watson.

10. On information and belief, Defendant Actavis plc is a public limited company existing under the laws of Ireland, having a principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland. On information and belief, Actavis plc's administrative headquarters are located at 400 Interpace Parkway, Parsippany, New Jersey, 07054. On information and belief, Actavis plc is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions and through the actions of its agents and subsidiaries, including, at least, Watson and Actavis, Inc.

11. Actavis plc's Form 10-K, filed on February 25, 2014 with the U.S. Securities and Exchange Commission, states that the majority of Actavis plc's R&D activities occur in, *inter alia*, Elizabeth, New Jersey. Actavis plc's February 25, 2014

Form 10-K also states that Actavis plc manufactures many of its finished products in Elizabeth, New Jersey.

12. On information and belief, Actavis plc owns property, including facilities used for manufacturing, R&D, and/or administrative functions, in New Jersey.On information and belief, Actavis, Inc. is a wholly-owned subsidiary of Actavis plc.

13. On information and belief, Actavis, Inc. acts at the direction of, under the control of, and for the benefit of Actavis plc and is controlled and/or dominated by Actavis plc.

14. On information and belief, Actavis plc and Actavis, Inc. have at least one officer and/or director in common.

15. On information and belief, Actavis, Inc. is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under Registration Number 5003854.

16. On information and belief, Actavis, Inc. is registered with the State of New Jersey, Division of Revenue and Enterprise Services, as Entity No. 0101005391 (Morristown, NJ).

17. On information and belief, Watson is a wholly-owned subsidiary of Actavis, Inc.

18. On information and belief, Watson acts at the direction of, under the control of, and for the benefit of Actavis, Inc. and is controlled and/or dominated by Actavis, Inc.

19. On information and belief, Watson and Actavis, Inc. have at least one officer and/or director in common.

20. On information and belief, Watson is within the control of Actavis, Inc. and Actavis plc for purposes of responding to discovery in this action.

21. On information and belief, Actavis, Inc. organizes its operations by divisions—including at least Generics, Brands, and Distribution.

22. On information and belief, Actavis, Inc.'s Generics division is involved in the development, manufacture, marketing, sale, and distribution of generic pharmaceuticals.

23. On information and belief, the Generics Division prepares Abbreviated New Drug Applications ("ANDAs") which are submitted to the FDA, relying on contributions from other agents and/or subsidiaries, including, at least, Watson.

24. On information and belief, each Defendant acts as an agent of the other, is a member and/or part of, and/or works in concert with each other as integrated parts of the Generics Division.

25. On information and belief, the head of the Generics Division is an employee of Actavis, Inc., the Generic Division's products are developed and manufactured by, at least, Watson, and the Generic Division's products are marketed, sold, and distributed throughout the United States, including in New Jersey, by at least Watson.

26. On information and belief, each Defendant shares with the others at least some common employees, officers, and directors.

27. On information and belief, Defendants participated and collaborated in the research and development, and the preparation and filing, of Watson's ANDA No. 204623 (or Watson's ANDA No. 207,238—both numbers are identified in the Watson Notification referenced in paragraph 48 *infra*) ("the Watson ANDA") for diclofenac sodium topical solution 2% w/w ("the Watson Product"), continue to participate and collaborate in seeking FDA approval of that application, and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale and sale of the Watson Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Watson's ANDA.

28. On information and belief, Watson has not contested, or has otherwise submitted to, the jurisdiction of this Court in at least 13 prior District of New Jersey actions: *Supernus Pharms., Inc. v. Actavis, Inc. et al.*, Civil Action No. 14-6102; *Supernus Pharms., Inc. v. Actavis, Inc. et al.*, Civil Action No. 14-1981; *Supernus Pharms., Inc. v. Actavis, Inc. et al.*, Civil Action No. 13-4740; *Auxilium Pharms., Inc. et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-3084; *Warner Chilcott Co. v. Watson Labs., Inc.*, Civil Action No. 12-2928; *Janssen Pharms., Inc, et al. v. Watson Labs., Inc., et al.*, Civil Action No. 08-5103; *Duramed Pharms. v. Watson Pharma, Inc, et al.*, Civil Action No. 07-5941; *Hoffman La-Roche Inc, et al. v. Cobalt Pharms. Inc., et al.*, Civil Action No. 07-4539; *Sanofi-Aventis et al. v. Watson Pharms., Inc., et al.*, Civil Action No. 07-443; *Warner Chilcott Co. v. Watson Pharms., Inc., et al.*, Civil Action No. 07-4697; *Novartis Corp. et al. v. Watson Labs., Inc., et al.*, Civil Action No. 06-1130; *Schering Corp. v. Zydus Pharms., USA, Inc., et al.*, Civil Action No. 06-4715; *Warner Chilcott Co. v. Watson Pharms., Inc., et al.*, Civil Action No. 06-3491.

29. On information and belief, Watson has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least four prior District of New Jersey actions: *Celgene Corp. v. Natco Pharma Ltd. et al.*, Civil Action No. 2:14-3126; *Bayer Pharma AG et al. v. Watson Labs., Inc. et al*, Civil Action No. 14-1804; *Auxilium Pharms., Inc. v. Watson Labs, Inc. et al.*, Civil Action No. 12-3084; *Shire LLC et al. v. Watson Labs., Inc.*, Civil Action No. 12-0083.

30. On information and belief, Actavis, Inc. has not contested, or has otherwise submitted to, the jurisdiction of this Court in at least nine prior District of New Jersey actions: *Astrazeneca AB et al. v. Watson Labs., Inc. – Florida, et al.*, Civil Action No. 13-3038; *Auxilium Pharms., Inc. et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084;[1] *Depomed, Inc. v. Actavis Elizabeth LLC et al.*, Civil Action No. 12-1358; *Noven Pharms. v. Watson Labs., Inc. et al.*, Civil Action No. 11-5997;[2] *Shire LLC, et al. v. Amneal Pharms. LLC et al.*, Civil Action No. 11-3781; *King Pharms. Inc. et al. v.*

[1] Watson Pharmaceuticals, Inc. submitted to the jurisdiction of this Court on July 6, 2012. Watson Pharmaceuticals, Inc. thereafter changed its name to Actavis, Inc.
[2] Watson Pharmaceuticals, Inc. submitted to the jurisdiction of this Court on November 4, 2011. Watson Pharmaceuticals, Inc. thereafter changed its name to Actavis, Inc.

Actavis, Inc. et al., Civil Action No. 09-6585; *Shire LLC v. Actavis South Atlantic, LLC et al.*, Civil Action No. 09-479; *King Pharms. Inc. et al. v. Actavis, Inc. et al.*, Civil Action No. 07-5041; *Sanofi-Aventis U.S. LLC et al. v. Actavis Totowa LLC et al.*, Civil Action No. 07-3142).

31. On information and belief, Actavis, Inc. has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least one prior District of New Jersey action: *Auxilium Pharms., Inc. et al. v. Watson Labs., Inc. et al.*, Civil Action No. 12-3084.

32. On information and belief, Actavis plc has not contested, or has otherwise submitted to, the jurisdiction of this Court in at least one prior District of New Jersey action: *Supernus Pharms., Inc. v. Actavis, Inc.*, Civil Action No. 14-6102.

JURISDICTION AND VENUE

33. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

34. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, their presence in New Jersey, having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law such that they should reasonably anticipate being haled into court in this judicial district, previously submitting to personal jurisdiction in this Court, availing themselves of the jurisdiction of this Court (*e.g.*, by the assertion of counterclaims), and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of generic drugs throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of generic drug products, including Watson products, within this judicial district, and through their intent to market and sell the Watson Product, if approved, to residents of this judicial district.

35. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

THE PATENTS-IN-SUIT

36. On July 10, 2012, the U.S. Patent and Trademark Office ("USPTO") duly and legally issued the '078 patent entitled "Treatment of Pain with Topical Diclofenac." At the time of its issue, the '078 patent was assigned to Nuvo Research Inc., which later assigned the '078 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '078 patent, which discloses and claims, *inter alia*, a method of applying topical agents to a knee of a patient with pain. A true and correct copy of the '078 patent is attached hereto as Exhibit A.

37. On August 28, 2012, the USPTO duly and legally issued the '838 patent entitled "Diclofenac Topical Formulation." At the time of its issue, the '838 patent was assigned to Nuvo Research Inc., which later assigned the '838 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '838 patent, which discloses and claims, *inter alia*, a pharmaceutical formulation containing diclofenac sodium. A true and correct copy of the '838 patent is attached hereto as Exhibit B.

38. On October 1, 2013, the USPTO duly and legally issued the '450 patent entitled "Treatment of Pain with Topical Diclofenac Compounds." At the time of its issue, the '450 patent was assigned to Nuvo Research Inc., which later assigned the '450 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '450 patent, which discloses and claims, *inter alia*, a method of treating a patient with combination therapy comprising administering a therapeutically effective amount of an oral NSAID and applying a topical diclofenac preparation to a knee. A true and correct copy of the '450 patent is attached hereto as Exhibit C.

39. On October 22, 2013, the USPTO duly and legally issued the '613 patent entitled "Diclofenac Topical Formulation." At the time of its issue, the '613 patent was assigned to Nuvo Research Inc., which later assigned the '613 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '613 patent, which discloses and claims, *inter alia*, a pharmaceutical

formulation containing diclofenac sodium. A true and correct copy of the '613 patent is attached hereto as Exhibit D.

40. On December 31, 2013, the USPTO duly and legally issued the '164 patent entitled "Treatment of Pain with Topical Diclofenac Compounds." At the time of its issue, the '164 patent was assigned to Nuvo Research Inc., which later assigned the '164 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '164 patent, which discloses and claims, *inter alia*, a method for applying topical agents to a knee of a patient with pain. A true and correct copy of the '164 patent is attached hereto as Exhibit E.

41. On October 28, 2014, the USPTO duly and legally issued the '809 patent entitled "Diclofenac Topical Formulation." At the time of its issue, the '809 patent was assigned to Nuvo Research Inc., which later assigned the '809 patent to HZNP Limited. HZNP Limited currently is the sole assignee and owner of all right, title and interest in and to the '809 patent, which discloses and claims, *inter alia*, a pharmaceutical formulation containing diclofenac sodium. A true and correct copy of the '809 patent is attached hereto as Exhibit F.

PENNSAID® 2%

42. Horizon Pharma Ireland Limited will be, pursuant to contractual obligation, the owner of FDA-approved New Drug Application No. 204623 ("the PENNSAID® 2% NDA") for diclofenac sodium topical solution 2% w/w (PENNSAID® 2%), which is sold in the US under the tradename PENNSAID®, and which will be sold by Horizon Pharma USA, Inc.

43. The PENNSAID® 2% solution is currently approved by the FDA for the relief of pain of osteoarthritis of the knees.

44. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '078, '838, '450, '613, '164 and '809 patents are listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the PENNSAID® 2% NDA.

45. The ’078, ’838, ’450, ’613, ’164 and ’809 patents cover PENNSAID® 2%.

WATSON’S ANDA

46. On information and belief, Watson submitted the Watson ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market diclofenac sodium topical solution 2% w/w. On information and belief, the Watson ANDA seeks approval to market the Watson Product for the relief of pain of osteoarthritis of the knees.

47. On information and belief, the Watson ANDA refers to and relies upon the PENNSAID® 2% NDA and contains data that, according to Watson, demonstrate the bioequivalence of the Watson Product and PENNSAID® 2%.

48. HZNP Limited received from Watson a letter, dated November 12, 2014 (the “Watson Notification”), stating that Watson had included a certification in the Watson ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the ’078, ’838, ’450, ’613 and ’164 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Watson Product (the “Paragraph IV Certification”).

49. The Watson Notification states that the Watson ANDA seeks approval to engage in the commercial manufacture, use or sale of diclofenac sodium topical solution 2% before the expiration of the ’078, ’838, ’450, ’613 and ’164 patents.

50. The ’809 patent was not addressed in the Watson Notification.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,217,078

51. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-50 of this Complaint.

52. Defendants have infringed the ’078 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Watson Product prior to the expiration of the ’078 patent.

53. Defendants’ commercial manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson Product into the

United States, during the term of the '078 patent also would infringe the '078 patent under 35 U.S.C. § 271(a), (b) and/or (c).

54. Upon approval of the Watson ANDA, and the commercial marketing thereof, Defendants will actively induce and/or contribute to infringement of the '078 patent.

55. This action is being filed within 45 days of receipt by Plaintiffs of the Watson Notification dated November 12, 2014, which purportedly advised Plaintiffs of Watson's Paragraph IV Certification filed relative to the '078 patent.

56. Upon information and belief, Defendants had actual and constructive notice of the '078 patent prior to filing Watson's ANDA, and Defendants' infringement of the '078 patent has been, and continues to be, willful.

57. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration of the '078 patent, or any later expiration of any exclusivity or extension of the '078 patent to which Plaintiffs or the patent may become entitled.

58. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '078 patent.

59. Plaintiffs have no adequate remedy at law.

60. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 8,252,838

61. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-60 of this Complaint.

62. Defendants have infringed the '838 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Watson Product prior to the expiration of the '838 patent.

63. Defendants' commercial manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson Product into the United States, during the term of the '838 patent also would infringe the '838 patent under 35 U.S.C. § 271(a), (b) and/or (c).

64. Upon approval of the Watson ANDA, and the commercial marketing of the Watson Product, Defendants will actively induce and/or contribute to infringement of the '838 patent.

65. This action is being filed within 45 days of receipt by Plaintiffs of the Watson Notification dated November 12, 2014, which purportedly advised Plaintiffs of Watson's Paragraph IV Certification field relative to the '838 patent.

66. Upon information and belief, Defendants had actual and constructive notice of the '838 patent prior to filing Watson's ANDA, and Defendants' infringement of the '838 patent has been, and continues to be, willful.

67. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration of the '838 patent, or any later expiration of any exclusivity or extension of the '838 patent to which Plaintiffs or the patent may become entitled.

68. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '838 patent.

69. Plaintiffs have no adequate remedy at law.

70. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,546,450

71. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-70 of this Complaint.

72. Defendants have infringed the '450 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA which seeks approval from the FDA to

engage in the commercial manufacture, use, offer to sell, sale or importation of the Watson Product prior to the expiration of the '450 patent.

73. Defendants' commercial manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson Product into the United States, during the term of the '450 patent also would infringe the '450 patent under 35 U.S.C. § 271(a), (b) and/or (c).

74. Upon approval of the Watson ANDA, and commercialization of the Watson Product, Defendants will actively induce and/or contribute to infringement of the '450 patent.

75. This action is being filed within 45 days of receipt by Plaintiffs of the Watson Notification dated November 12, 2014, which purportedly advised Plaintiffs of Watson's Paragraph IV Certification filed relative to the '450 patent.

76. Upon information and belief, Defendants had actual and constructive notice of the '450 patent prior to filing Watson's ANDA, and Defendants' infringement of the '450 patent has been, and continues to be, willful.

77. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration of the '450 patent, or any later expiration of any exclusivity or extension of the '450 patent to which Plaintiffs or the patent may become entitled.

78. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '450 patent.

79. Plaintiffs have no adequate remedy at law.

80. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 8,563,613

81. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-80 of this Complaint.

82. Defendants have infringed the '613 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Watson Product prior to the expiration of the '613 patent.

83. Defendants' commercial manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson Product into the United States, during the term of the '613 patent, would further infringe the '613 patent under 35 U.S.C. § 271(a), (b) and/or (c).

84. Upon approval of the Watson ANDA, and commercial marketing of the Watson Product, Defendants will actively induce and/or contribute to the infringement of the '613 patent.

85. This action is being filed within 45 days of receipt by Plaintiffs of the Watson Notification dated November 12, 2014, which purportedly advised Plaintiffs of Watson's Paragraph IV Certification with respect to the '613 patent.

86. Upon information and belief, Defendants had actual and constructive notice of the '613 patent prior to filing Watson's ANDA, and Defendants' infringement of the '613 patent has been, and continues to be, willful.

87. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration of the '613 patent, or any later expiration of any exclusivity or extension of the '613 patent to which Plaintiffs or the patent may become entitled.

88. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '613 patent.

89. Plaintiffs have no adequate remedy at law.

90. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 8,618,164

91. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-90 of this Complaint.

92. Defendants have infringed the '164 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Watson ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Watson Product prior to the expiration of the '164 patent.

93. Defendants' commercial manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson Product into the United States during the term of the '164 patent also would infringe the '164 patent under 35 U.S.C. § 271(a), (b) and/or (c).

94. Upon approval of the Watson ANDA, and commercialization of the Watson Product, Defendants will actively induce and/or contribute to infringement of the '164 patent.

95. This action is being filed within 45 days of receipt by Plaintiffs of the Watson Notification dated November 12, 2014, which purportedly advised Plaintiffs of Watson's Paragraph IV Certification filed relative to the '164 patent.

96. Upon information and belief, Defendants had actual and constructive notice of the '164 patent prior to filing Watson's ANDA, and Defendants' infringement of the '164 patent has been, and continues to be, willful.

97. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's ANDA be a date that is not earlier than the expiration of the '164 patent, or any later expiration of any exclusivity or extension of '164 patent to which Plaintiffs or the patent may become entitled.

98. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '164 patent.

99. Plaintiffs have no adequate remedy at law.

100. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VI FOR INFRINGEMENT OF U.S. PATENT NO. 8,871,809

101. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-100 of this Complaint.

102. The '809 patent is a continuation of U.S. patent applications that matured into the '613 and '838 patents.

103. The application that matured into the '809 patent was published as US 2014/0018427A1 on January 16, 2014.

104. The '809 patent issued on October 28, 2014, and expires on October 17, 2027.

105. Defendants have previously filed certifications in the Watson ANDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to market the Watson Product prior to the expiration of, *inter alia*, the '613 patent, which expires on October 17, 2027. Because the '809 patent also expires on October 17, 2027, Defendants seek approval of the Watson ANDA, and to market the Watson Product, prior to the expiration of the '809 patent.

106. By submitting and seeking approval of the Watson ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Watson Product, prior to the date the'809 patent expires, Defendants have infringed the '809 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

107. Defendants' commercial manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson Product into the United States, during the term of the '809 patent, also would infringe the '809 patent under 35 U.S.C. § 271(a), (b) and/or (c).

108. Upon approval of the Watson ANDA, and commercialization of the Watson Product, Defendants will actively induce and/or contribute to infringement of the '809 patent.

109. Upon information and belief, Defendants had actual and constructive notice of the '809 patent prior to sending the Watson Notification, and Defendants' infringement of the '809 patent has been, and continues to be, willful.

110. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Watson's

ANDA be a date that is not earlier than the expiration of the '809 patent, or any later expiration of any exclusivity or extension of the '809 patent to which Plaintiffs or the patent may become entitled.

111. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '809 patent.

112. Plaintiffs have no adequate remedy at law.

113. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VII FOR DECLARATION OF INFRINGEMENT OF U.S. PATENT NO. 8,871,809

114. Plaintiffs reallege and incorporate by reference the allegations of paragraphs 1-113 of this Complaint.

115. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

116. There currently exists an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

117. Defendants' commercial manufacture, use, offer to sell, or sale of the Watson Product within the United States, or importation of the Watson Product into the United States, during the term of the '809 patent, would infringe the '809 patent.

118. Defendants seek approval of the Watson ANDA, and to market the Watson Product, prior to the expiration of the '809 patent.

119. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import the Watson Product prior to the expiration of the '809 patent.

120. Plaintiffs are entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of the Watson Product prior to the expiration of the '809 patent by Defendants would constitute direct infringement, contributory infringement, and/or active inducement of infringement of the '809 patent.

121. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the ’809 patent.

122. Plaintiffs have no adequate remedy at law.

123. This case is exceptional, and Plaintiffs are entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants, and respectfully request the following relief:

A. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,217,078;

B. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,252,838;

C. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,546,450;

D. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,563,613;

E. A judgment declaring that Defendants have infringed one or more claims of U.S. Patent No. 8,618,164;

F. A judgment declaring that Defendants have infringed and will infringe one or more claims of U.S. Patent No. 8,871,809;

G. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Watson Product within the United States, or importing the Watson Product into the United States, prior to the expiration date of the ’078 patent;

H. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives,

agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Watson Product within the United States, or importing the Watson Product into the United States, prior to the expiration date of the ’838 patent;

I. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Watson Product within the United States, or importing the Watson Product into the United States, prior to the expiration date of the ’450 patent;

J. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Watson Product within the United States, or importing the Watson Product into the United States, prior to the expiration date of the ’613 patent;

K. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, from manufacturing, using, offering to sell, or selling the Watson Product within the United States, or importing the Watson Product into the United States, prior to the expiration date of the ’164 patent;

L. A declaration pursuant to 28 U.S.C. § 2201 that if Defendants, their officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, manufacture, use, offer to sell, or sell the Watson Product within the United States, or import the Watson Product into the

United States, prior to the expiration date of the '809 patent, it will constitute an act of infringement of the '809 patent;

M. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Product within the United States, or import the Watson Product into the United States, prior to the expiration of the '078 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

N. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Product within the United States, or import the Watson Product into the United States, prior to the expiration of the '838 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

O. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Product within the United States, or import the Watson Product into the United States, prior to the expiration of the '450 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

P. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Product within the United States, or import the Watson Product into the United States, prior to the expiration of the '613 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

Q. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Product within the United States, or import the Watson Product into the United States, prior to the expiration of the '164 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

R. If Defendants commercially manufacture, use, offer to sell, or sell the Watson Product within the United States, or import the Watson Product into the United States, prior to the expiration of the '809 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;

S. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Watson ANDA shall be a date not earlier than the expiration date of the '078, '838, '450, '613, '164 and/or '809 patents, inclusive of any extensions;

T. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

U. Costs and expenses in this action; and

V. Such other and further relief as the Court deems just and proper.

Date: December 23, 2014

s/John E. Flaherty

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

The undersigned certifies that United States Patent Nos. 8,217,078, 8,546,450, 8,618,164, and 8,741,956, asserted (among other patents) in the accompanying Complaint, are subjects of the following pending lawsuit which pertains to a pharmaceutical product that is different from the product involved in the accompanying Complaint:

- *Mallinckrodt LLC, et al. v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 14-cv-04901-JEI-AMD (D.N.J.)

Date: December 23, 2014

s/John E. Flaherty

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